Immunoglobulin G FS*

Diagnostic reagent for quantitative in vitro determination of immunoglobulin G (IgG) in serum or plasma on DiaSys respons®920

Order Information
Cat. No. 17212 99 10 921
4 twin containers for 80 tests each

Method
Immunoturbidimetric test

Principle
Determination of IgG concentration by photometric measurement of antigen-antibody-reaction of antibodies against human IgG and IgG present in the sample.

Reagents
Components and Concentrations
R1: TRIS pH 7.5 100 mmol/L
NaCl 150 mmol/L
R2: TRIS pH 8.0 100 mmol/L
NaCl 300 mmol/L
Anti-human IgG antibody (goat) <1%.

Storage Instructions and Reagent Stability
The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C, protected from light and contamination is avoided. DiaSys respons containers provide protection from light. Do not freeze the reagents!

Warnings and Precautions
1. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes!
2. Reagent 2 contains animal material. Handle the product as potentially infectious according to universal precautions and good laboratory practice.
3. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons®920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
4. In very rare cases, samples of patients with gammopathy might give falsified results [8].
5. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient’s medical history, clinical examinations and other findings.
6. For professional use only.

Waste Management
Please refer to local legal requirements.

Reagent Preparation
The reagents are ready to use. The bottles are placed directly into the reagent rotor.

Specimen
Serum, heparin plasma or EDTA plasma
Stability[1]:
3 months at 20 – 25°C
3 months at 4 – 8°C
6 months at 20 – 8°C
Discard contaminated specimens. Freeze only once.

Calibrators and Controls
DiaSys TruCal Protein calibrator set is recommended for calibration. The assigned values of the calibrators have been made traceable to the Reference Material ERM®-DA470k/IFCC. For internal quality control DiaSys TruLab Protein controls should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

TruCal Protein (5 levels) 5 0200 99 10 039 5 x 1 mL
TruLab Protein level 1 5 9500 99 10 046 3 x 1 mL
TruLab Protein level 2 5 9510 99 10 046 3 x 1 mL

Performance Characteristics
Measuring range up to 3200 mg/dL IgG, at least up to the concentration of the highest calibrator (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or rerun function).

Limit of detection** 2 mg/dL IgG
No prozone effect up to 8000 mg/dL IgG
On-board stability 30 days
Calibration stability 10 days

Interfering substance Interferences IgG [mg/dL]
Hemoglobin up to 600 mg/dL 384
up to 1200 mg/dL 1741
Bilirubin, conjugated up to 60 mg/dL 392
up to 60 mg/dL 1843
Bilirubin, unconjugated up to 60 mg/dL 391
up to 60 mg/dL 1844
Lipemia (triglycerides) up to 2000 mg/dL 382
up to 2000 mg/dL 1541

No cross reaction with IgA and IgM was observed.
For further information on interfering substances refer to Young DS [2].

Conversion factor
Immunoglobulin G [mg/dL] x 0.067 = Immunoglobulin G [μmol/L]

Reference Range
Adults [3]
Newborns 700 – 1600 mg/dL 46.9 – 107 μmol/L
1 – 3 month(s) 250 – 750 mg/dL 16.8 – 50.3 μmol/L
4 – 6 month(s) 180 – 800 mg/dL 12.3 – 53.6 μmol/L
7 – 12 month(s) 300 – 1000 mg/dL 20.1 – 67.0 μmol/L
2 years 350 – 1000 mg/dL 23.5 – 67.0 μmol/L
3 – 5 years 500 – 1300 mg/dL 33.5 – 87.1 μmol/L
6 – 9 years 600 – 1300 mg/dL 40.2 – 87.1 μmol/L
10 – 13 years 700 – 1400 mg/dL 46.9 – 93.8 μmol/L

Children [4]

<table>
<thead>
<tr>
<th>Sample 1</th>
<th>Sample 2</th>
<th>Sample 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean [mg/dL]</td>
<td>864</td>
<td>1127</td>
</tr>
<tr>
<td>Coefficient of variation [%]</td>
<td>2.42</td>
<td>3.71</td>
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<tr>
<td>Coefficient of correlation</td>
<td>0.997</td>
<td></td>
</tr>
</tbody>
</table>

Method comparison (n=128)
Test x DiaSys Immunoglobulin G FS Hitachi 917
Test y DiaSys Immunoglobulin G FS respons®920
Slope 0.983
Intercept 20.9 mg/dL

* according to NCCCLS document EP17-A, vol. 24, no. 34

Manufacturers
DiaSys Diagnostic Systems GmbH
Alte Strasse 9
65558 Holzheim
Germany

Literature
# Immunoglobulin G FS

**Application for serum and plasma**

### Test Details

<table>
<thead>
<tr>
<th>Test</th>
<th>IGG</th>
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<tbody>
<tr>
<td>Report Name</td>
<td>Immunoglobulin G</td>
</tr>
<tr>
<td>Unit</td>
<td>mg/dL</td>
</tr>
<tr>
<td>Wavelength-Primary</td>
<td>578</td>
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<tr>
<td>Assay Type</td>
<td>2-Point</td>
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<tr>
<td>M1 Start</td>
<td>15</td>
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<tr>
<td>M2 Start</td>
<td>33</td>
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<tr>
<td>Sample Replicates</td>
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</tr>
<tr>
<td>Control Replicates</td>
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<tr>
<td>Reaction Direction</td>
<td>Increasing</td>
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<tr>
<td>Prozone Limit %</td>
<td>97</td>
</tr>
<tr>
<td>Technical Limit</td>
<td>*</td>
</tr>
<tr>
<td>Y = aX + b</td>
<td>a= 1.00</td>
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</tbody>
</table>

### Test Volumes

<table>
<thead>
<tr>
<th>Sample Type</th>
<th>Serum</th>
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<tbody>
<tr>
<td>Normal</td>
<td>2.00 µL</td>
</tr>
<tr>
<td>Increase</td>
<td>4.00 µL</td>
</tr>
<tr>
<td>Decrease</td>
<td>2.00 µL</td>
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<tr>
<td>Standard Volume</td>
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### Reference Ranges

<table>
<thead>
<tr>
<th>Category</th>
<th>Male</th>
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<tbody>
<tr>
<td>Normal</td>
<td>700.00</td>
</tr>
<tr>
<td>Panic</td>
<td>0.00</td>
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</tbody>
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*Technical Limits are automatically defined by software via upper and lower calibrator level.

** Enter calibrator value.